

Amendment and Response Under 37 C.F.R. §1.116 - Expedited Examining Procedure

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Serial No.: 09/738,599

Confirmation No.: 1240

Filed: December 15, 2000

For: NUCLEIC ACID ENCODING AN AVIAN E. COLI ISS POLYPEPTIDE AND METHODS OF USE

Amendments to the Claims

Please amend claims 35, 37, 38, 41, 42, 46, 48, 57-59, 61, 63, and 67, and add new claims 68-70. For convenience, all pending claims are shown below.

1-29. (Canceled)

30. (Previously Presented) An isolated nucleic acid molecule comprising nucleotides 73 to 309 of the nucleotide sequence SEQ ID NO:22.

31. (Previously Presented) The isolated nucleic acid molecule of claim 30 further comprising nucleotides 1 to 33 of the nucleotide sequence SEQ ID NO:21, wherein the 33 nucleotides of the nucleotide sequence SEQ ID NO:21 are located 5' of nucleotides 73 to 309 of the nucleotide sequence SEQ ID NO:22.

32. (Previously Presented) The isolated nucleic acid molecule of claim 30 wherein nucleotides 73 to 309 of the nucleotide sequence SEQ ID NO:22 is operably linked to a promoter functional in a host cell so as to form an expression vector.

33. (Previously Presented) An expression vector comprising an isolated nucleic acid molecule comprising nucleotides 73 to 309 of the nucleotide sequence SEQ ID NO:22, operably linked to at least one regulatory sequence or control sequence.

34. (Canceled)

35. (Withdrawn-Currently Amended) A method of using a nucleic acid molecule encoding an *E. coli* Iss polypeptide, the method comprising:

providing a host cell stably transformed with an expression vector comprising a nucleic acid molecule of claim 30 ~~comprising nucleotides 73 to 309 of the nucleotide sequence SEQ ID~~

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NO:22, operably linked to a least one regulatory sequence or control sequence ~~recognized~~
recognized by the host cell; and

expressing the nucleic acid molecule to yield an *E. coli* Iss polypeptide.

36. (Withdrawn) The method of claim 35 wherein the nucleic acid molecule further comprises nucleotides 1 to 33 of the nucleotide sequence SEQ ID NO:21 located 5' of nucleotides 73 to 309 of the nucleotide sequence SEQ ID NO:22.

37. (Currently Amended) An immunogenic composition comprising:

new [[a]] an isolated nucleic acid molecule comprising a nucleotide sequence encoding a polypeptide comprising an avian *E. coli* Iss polypeptide or an immunogenic fragment or immunogenic subunit thereof, wherein the nucleic acid molecule further comprises at least one regulatory sequence or control sequence operably linked to the nucleotide sequence encoding the polypeptide; and

a pharmaceutically acceptable carrier.

38. (Currently Amended) The immunogenic composition of claim 37 wherein the nucleic acid molecule is included in ~~comprises~~ a vector.

39. (Original) The immunogenic composition of claim 38 wherein the vector is a plasmid.

40. (Original) The immunogenic composition of claim 38 wherein the vector is a viral vector.

41. (Currently Amended) The immunogenic composition of claim 37 wherein the ~~nucleic acid molecule further comprises~~ at least one regulatory sequence or control sequence ~~operably linked to the nucleotide sequence encoding~~ causes expression of the polypeptide in an animal cell.

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42. (Currently Amended) The immunogenic composition of claim 38 wherein the nucleic acid molecule further comprises an immunostimulatory nucleotide sequence.

43. (Previously Presented) The immunogenic composition of claim 38 wherein the nucleic acid molecule comprises nucleotides 73 to 309 of the nucleotide sequence SEQ ID NO:22 or an immunogenic subunit or immunogenic fragment thereof.

44. (Previously Presented) The immunogenic composition of claim 38 wherein the nucleic acid molecule comprises nucleotides 73 to 309 of the nucleotide sequence SEQ ID NO:22.

45. (Previously Presented) The immunogenic composition of claim 43 wherein the nucleic acid molecule further comprising nucleotides 1 to 33 of the nucleotide sequence SEQ ID NO:21 located 5' of nucleotides 73 to 309 of the nucleotide sequence SEQ ID NO:22.

46. (Withdrawn-Currently Amended) A method for using an immunogenic composition comprising:

providing an the immunogenic composition comprising a nucleic acid molecule comprising a nucleotide sequence encoding a polypeptide comprising an avian *E. coli* Iss polypeptide or an immunogenic fragment or subunit thereof of claim 37; and

administering the immunogenic composition to a subject diagnosed with, at risk of, or exhibiting symptoms of an *E. coli* infection.

47. (Withdrawn) The method of claim 46 wherein the *E. coli* infection is selected from the group consisting of septicemic disease, colibacillosis, coligranuloma, peritonitis, salpingitis, synovitis, and omphalitis.

48. (Withdrawn-Currently Amended) The method of claim 46 wherein the nucleic acid molecule is included in comprises a vector.

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49. (Withdrawn) The method of claim 48 wherein the vector is a plasmid.
50. (Withdrawn) The method of claim 48 wherein the vector is a viral vector.
51. (Withdrawn) The method of claim 46 wherein the nucleic acid molecule further comprises at least one regulatory sequence or control sequence operably linked to the nucleotide sequence encoding the polypeptide.
52. (Withdrawn) The method of claim 46 wherein the nucleic acid molecule further comprises an immunostimulatory sequence.
53. (Withdrawn) The method of claim 46 wherein the nucleic acid molecule comprises nucleotides 73 to 309 of SEQ ID NO:22 or a subunit or fragment thereof.
54. (Withdrawn) The method of claim 53 wherein the nucleic acid molecule comprises nucleotides 73 to 309 of SEQ ID NO:22.
55. (Withdrawn) The method of claim 53, the nucleic acid molecule further comprising nucleotides 1 to 33 of SEQ ID NO:21 located 5' of nucleotides 73 to 309 of SEQ ID NO:22.
56. (Withdrawn) The method of claim 46 wherein the subject is selected from the group consisting of a bird, a cow and a mink.
57. (Withdrawn-Currently Amended) A method for making an immunogenic composition, the method comprising combining a pharmaceutically acceptable carrier and [[a]] the isolated nucleic acid molecule comprising a nucleotide sequence encoding a polypeptide comprising an avian *E. coli* iss polypeptide or an immunogenic fragment or subunit thereof of claim 30.

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58. (Withdrawn-Currently Amended) A method for vaccinating a subject comprising administering to the subject ~~a nucleic acid molecule comprising a nucleotide sequence encoding a polypeptide comprising an *E. coli* Iss polypeptide or an immunogenic fragment or subunit thereof~~ the composition of claim 37 in an amount effective to result in an immune response that is specific for the Iss polypeptide.

59. (Withdrawn-Currently Amended) The method of claim 58 wherein the nucleic acid molecule is included in comprises a vector.

60. (Withdrawn) The method of claim 58 wherein the nucleic acid molecule further comprises a regulatory sequence or a control sequence operably linked to the nucleotide sequence encoding the polypeptide.

61. (Withdrawn-Currently Amended) The method of claim 58 wherein the nucleic acid molecule further comprises an immunostimulatory nucleotide sequence.

62. (Withdrawn) The method of claim 58 wherein the subject is selected from the group consisting of a bird, a cow or a mink.

63. (Withdrawn-Currently Amended) A method for treating or preventing disease in a subject caused by a complement resistant *E. coli* comprising administering to the subject a vaccine comprising [[a]] the isolated nucleic acid molecule ~~comprising a nucleotide sequence encoding a polypeptide comprising an *E. coli* Iss polypeptide or an immunogenic fragment or subunit thereof~~ of claim 30.

64. (Withdrawn) The method of claim 63 wherein the nucleic acid molecule comprises a vector.

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65. (Withdrawn) The method of claim 63 wherein the nucleic acid molecule further comprises a regulatory sequence or a control sequence operably linked to the nucleotide sequence encoding the polypeptide.
66. (Withdrawn) The method of claim 65 wherein the nucleic acid molecule further comprises an immunostimulatory sequence.
67. (Currently Amended) The immunogenic composition of claim 43 wherein the immunogenic composition generates an antibody response against the polypeptide, subunit, or fragment when administered to a subject.
68. (New) An immunogenic composition comprising:
an isolated nucleic acid molecule comprising a nucleotide sequence encoding a polypeptide comprising an avian *E. coli* Iss polypeptide or an immunogenic fragment or immunogenic subunit thereof, wherein the nucleic acid molecule further comprises an immunostimulatory nucleotide sequence; and
a pharmaceutically acceptable carrier.
69. (New) An immunogenic composition comprising:
an isolated nucleic acid molecule comprising a nucleotide sequence comprising nucleotides 73 to 309 of the nucleotide sequence SEQ ID NO:22; and
a pharmaceutically acceptable carrier.
70. (New) An immunogenic composition comprising:
an isolated nucleic acid molecule comprising a nucleotide sequence encoding a polypeptide comprising an avian *E. coli* Iss polypeptide or an immunogenic fragment or immunogenic subunit thereof, wherein the nucleic acid molecule comprises nucleotides 73 to 309 of the nucleotide sequence SEQ ID NO:22 or an immunogenic subunit or immunogenic

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fragment thereof, and ; and wherein the nucleic acid molecule further comprising nucleotides 1 to 33 of the nucleotide sequence SEQ ID NO:21 located 5' of nucleotides 73 to 309 of the nucleotide sequence SEQ ID NO:22.

a pharmaceutically acceptable carrier.